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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,612	03/13/2001	Mie Takahashi	43890-475	7340

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WASHINGTON, DC 20005-3096

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/30/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/743,612

Applicant(s)

TAKAHASHI ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 7 "can take on" is vague and indefinite. It is unclear what applicant intends. Further, the recitation "can" is not a positive recitation.

Claim 1 is vague and indefinite because it is unclear if the coloration level measuring means requires one of either an optical measurement or an image measurement or both. For examination purposes Examiner interprets the coloration level means to require only one.

Claim 1 is vague and indefinite because it is unclear how the coloration is achieved. Does the binding reagent contain a label or does the reaction between the binding reagent and the analyte cause a chemical reaction, which produces the coloration? See also deficiencies found in claims 15 and 22. Further, it is unclear how the analyte can be detected without the use of a label.

Claim 3, line 25, the phrase " - like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP

Art Unit: 1641

§ 2173.05(d). Please see deficiencies throughout the claims specifically the phrases "sheet-like", "dot-like" and "spots-like".

Claim 3, line 29 "can be" is vague and indefinite. The phrase "can be" is a conditional phrase and is not a positive recitation. See also deficiencies found in claims 10, 21, 22 and 27.

Claim 6, line 30 the recitation "all over" is vague and indefinite. It is unclear if the plurality of reaction areas form a continuous film that covers the reactive layer or if the plurality of reaction areas are randomly placed at different locations throughout the reactive layer. See deficiencies found throughout the claims.

Claim 7, line 5 and 6 is vague and indefinite because it is unclear how a liquid sample can be moistened.

Claim 9, line 24 the recitation "capable of" is vague and indefinite. The recitation "capable of" is not a positive limitation but only requires the ability to so perform. See also deficiencies found in claims 14, 15, 21, 22 and 27.

Claim 15, line 19 "a condition of" is vague and indefinite. It is unclear what is considered to be a condition of coloration (i.e. a coloration change, an arrangement of color, an increase or decrease). See deficiencies throughout the claims.

Claim 15, line 20 "being taken on" is vague and indefinite. It is unclear what applicant intends.

Claim 15, line 24 "subjecting" is vague and indefinite. It is unclear what applicant intends.

Art Unit: 1641

Claim 22, line 25 "has a nature" is vague and indefinite. It is unclear what applicant is trying to encompass (i.e. does the binding reagent have a certain structure or does the binding reagent contain a label or is applicant referring to something else)?

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 8, 9 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Sommer et al (US 5,569,608 ).

Sommer et al disclose a method and device for determining the concentration of an analyte in a test fluid by immunochromatography. Sommer et al disclose a chromatographic strip, which comprises a plurality of reaction areas (see figures 3 and 5). Sommer et al disclose immobilized binding reagent in the reaction areas. Sommer et al also disclose the use of an instrument to detect reflectance of light from the labeled binding partner and quantitatively determining the concentration of analyte (col 2, lines 5-63).

Art Unit: 1641

5. Claims 1, 2, 8, 9, 15 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuo et al (US 6,183,972).

Kuo et al disclose a method and device for determining the concentration of an analyte in a test fluid by immunochromatography. Kuo et al disclose applying a sample to a test matrix, which can be in the form of a strip. Kuo et al disclose that the strip can be formed of non-bibulous or bibulous materials. Kuo et al disclose that the strip comprises a region having mobile specific binding partner for the analyte which bears a detectable label and can react with analyte present in the fluid to form an analyte/labeled binding partner complex. Kuo et al disclose detection regions (reaction areas) which contain immobilized antibodies specific for an epitope of the analyte. Kuo et al also disclose an absorbent pad on the test strip. Kuo et al disclose detecting the labeled antibody to quantitatively determine the concentration of analyte. Kuo et al disclose the antibody label is capable of reflecting light at a predetermined wavelength and providing a reflectance spectrometer having a detector of reflectance intensity with means for moving the developed strip and detector relative to each other such as a specimen table on which the strip is placed which can be moved laterally under the read head of the detector. Kuo et al disclose that this provides in providing accurate quantitation. Kuo et al disclose that the detector can be under microprocessor control and that desired regions can be determined and then combined with preprogrammed software to provide a monotonous dose-response curve for the quantitative determination of an analyte (col 3-5).

Art Unit: 1641

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 4, 6, 7, 10, 12-14, 16, 18-21, 23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al (US 6,183,972) in view of Chandler et al (US 6,271,046).

See above for teachings of Kuo et al.

Kuo et al differ from the instant invention in failing to specifically teach that the chromatographic strip includes a sheet-like solid support.

Chandler et al disclose an immunochromatographic test strip which comprises a backing sheet (sheet-like solid support). Chandler et al discloses that this backing sheet facilitates the advantage of handling of the immunchromatographic strip (col 7, lines 35-62).

It would have been obvious to one of ordinary skill in the art to incorporate a backing sheet as taught by Chandler et al into the chromatographic strip of Kuo et al because Chandler et al shows that such a backing sheet facilitates the advantage of handling the chromatographic strip.

8. Claims 5, 11, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al (US 6,183,972) in view of Chandler et al (US 6,271,046) as

Art Unit: 1641

applied to claims 1-4, 6-10, 12-16, 18-23 and 25-28 above, and further in view of Catt et al (US 6,235,241).

See above for teachings of Kuo et al and Chandler et al.

Kuo et al and Chandler et al differ from the instant invention in failing to teach the reaction areas have a plurality of spots.

Catt et al disclose the detectable material in a precisely-defined region (detection zone) can be placed in the form of a narrow line or dot (col 6). Catt et al disclose that the immobilization of specific binding reagent in this manner provides for a simple and cost effective manner for determining an analyte of interest.

It would have been obvious to one of ordinary skill in the art to incorporate the use of dot immobilized specific binding reagent as taught by Catt et al into the modified method and device of Kuo et al because Catt et al show that the immobilization of specific binding reagent in this manner provides for a simple and cost effective manner for determining an analyte of interest.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Brooks et al (US 5,753,517) disclose quantitative immunochromatographic assays for measuring the amount of analyte and an apparatus for use in the assays.

Sommer et al (EP 0724157) disclose a method for determining the concentration of analyte in test fluid by immunochromatography.

No claims are allowed.



Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
December 26, 2002



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12/27/02